Notice of Allowability	Application No.	Applicant(s)	
	09/926,001	SCHRODER ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *28 October 2004*.

2. ☒ The allowed claim(s) is/are *11-46, renumbered 1-36, respectively*.

3. ☒ The drawings filed on *13 August 2001* are accepted by the Examiner.

4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☒ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *3/21/2005* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

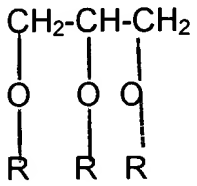
JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Allowance

1. This Office Action is responsive to Applicant's response filed October 28,2004.

2. All rejections of record are withdrawn in view of Applicant's Amendments and remarks. Claims 11-46 are allowed and have been renumbered as claims 1-36 respectively.

3. The following is an examiner's statement of reasons for allowance. The prior art cited neither teaches nor suggests a vaccine composition nor an aerosol or spray package comprising an adjuvant comprising one or more substances selected from the group consisting of: a) monoglyceride preparations having at least 80% monoglyceride content and having a formula



wherein R is H or an acyl group containing from 6 to 24 carbon atoms with the *proviso* that two of the R groups are H and b) a fatty acid with 6 to 24 carbons atoms and an immunizing component that is a heat-killed or formalin killed *Mycobacterium tuberculosis*. The instantly claimed vaccine formulation is novel and therefore, the method of vaccinating a mammal a mammal against *Mycobacterium* as instantly claimed is also novel.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

4. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
March 21, 2005

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Examiner's Amendment

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Richard E. Fichter on March 21, 2005.

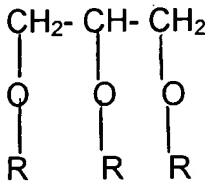
Please Amended the Application as follows:

In the Specification:

The first paragraph of the specification has been amended to include ----- This application claims priority to a 371 of PCT/EP00/01046, filed 09 February 2000. ----- .

In the Claims:

11 (currently amended). A Tuberculosis (TB) vaccine composition comprising ~~as~~ an adjuvant, comprising one or more substances selected from the group consisting of: a) monoglyceride preparations having at least 80% monoglyceride content and having a formula:



wherein R is H or an acyl group containing from 6 to 24 carbon atoms with the ~~proviso~~ *proviso* that two of the R groups are H and b) a fatty acid with 6 to 24 carbon atoms and as immunizing component, inactivated *Mycobacterium tuberculosis* bacteria.

12 (previously amended). The TB vaccine according to claim 11, wherein the *M. tuberculosis* bacteria are heat or formalin killed.

13 (previously presented). The TB vaccine composition according to claim 11, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 90%, and the acyl chains of the monoglyceride in the monoglyceride preparation contains 8 to 20 carbon atoms.

14 (previously presented). The TB vaccine composition according to claim 11, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 95% and the acyl chains of the monoglyceride in the monoglyceride preparation contains 14 to 20 carbon atoms.

15 (previously presented). The TB vaccine composition according to claim 11, which further comprises pharmaceutical excipients selected from the group consisting of biocompatible oils, physiological saline solutions, preservatives, osmotic pressure controlling agents, carrier gases, pH-controlling agents, organic solvents, hydrophobic agents, enzyme inhibitors, water absorbing polymers, surfactants, absorption promoters and anti-oxidative agents.

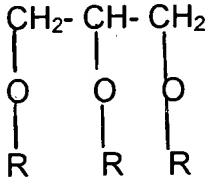
16 (previously amended). The TB vaccine composition according to claim 11, wherein the monoglyceride preparation is mono-olein and the fatty acid is oleic acid, and the immunizing component is heat-killed *M. tuberculosis* bacteria.

17 (previously presented). The TB vaccine composition according to claim 15, wherein the adjuvant further comprises soybean oil.

18 (previously presented). The TB vaccine composition according to claim 11, wherein the composition is formulated into a preparation for mucosal administration.

19 (previously presented). The TB vaccine composition according to claim 18, wherein the mucosal administration is nasal, pulmonary, oral or vaginal administration.

20 (currently amended). An aerosol or spray package comprising a TB vaccine composition comprising ~~as~~ an adjuvant, comprising one or more substances selected from the group consisting of: a) monoglyceride preparations having at least 80% monoglyceride content and having the formula:



wherein R is H or an acyl group containing from 6 to 24 carbon atoms with the ~~proviso~~ *proviso* that two of the R groups are H, and b) a fatty acid with 6 to 24 carbon atoms, and as immunizing component, inactivated *Mycobacterium tuberculosis* bacteria.

21 (previously amended). An aerosol or spray package according to claim 20. wherein the *M. tuberculosis* bacteria are heat or formalin killed.

22 (previously presented). An aerosol or spray package according to claim 20, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 90%, acyl chains of the monoglyceride in the monoglyceride preparation and contains 8 to 20 carbon atoms.

23 (previously presented). An aerosol or spray package according to claim 20, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 95% and the acyl chains of the monoglyceride preparation contains 14 to 20 carbon atoms.

24 (previously presented). An aerosol or spray package according to claim 20, which further comprises pharmaceutical excipients selected from the group consisting of biocompatible oils, physiological saline solutions, preservatives, osmotic pressure controlling agents, carrier oases, pH-controlling agents, organic solvents, hydrophobic agents, enzyme inhibitors, water absorbing polymers, surfactants, absorption promoters and anti-oxidative agents.

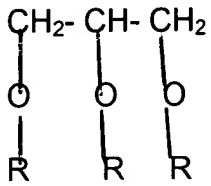
25. (previously amended). An aerosol or spray package according to claim 20, wherein the monoglyceride preparation is mono-olein and the fatty acid is oleic acid, and the immunizing component is heat-killed *M. tuberculosis* bacteria.

26. (previously presented). An aerosol or spray package according to claim 20, wherein the composition is formulated into a preparation for mucosal administration.

27 (previously presented). An aerosol or spray package according to claim 26, wherein the mucosal administration is nasal, pulmonary, oral or vaginal administration.

28 (previously amended). An aerosol or spray package according to claim 25, wherein the adjuvant further comprises soybean oil.

29 (currently amended). A nose-drop package comprising a TB vaccine composition comprising ~~as~~ an adjuvant, comprising one or more substances selected from the group consisting of: a) monoglyceride preparations having at least 80% monoglyceride content and having the general formula:



wherein R is H or an acyl group containing from 6 to 24 carbon atoms with the ~~proviso~~ *proviso* that two of the R groups are H, and b) a fatty acid with 6 to 24 carbon atoms; and as immunizing component, inactivated *Mycobacterium tuberculosis* bacteria.

30 (previously presented). The nose-drop package, according claims 29, wherein the *M. tuberculosis* bacteria are heat or formalin killed.

31 (previously presented). The nose-drop package according to claim 29, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 90% and the acyl chains of the monoglyceride in the monoglyceride preparation contains 8 to 20 carbon atoms.

32 (previously presented). The nose-drop package according to claim 29, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 95% and the acyl chains of the monoglyceride in the monoglyceride preparation contains 14 to 20 carbon atoms.

33 (previously presented). The nose-drop package according to claim 29, which further comprises pharmaceutical excipients selected from the group consisting of biocompatible oils, physiological saline solutions, preservatives, osmotic pressure controlling agents, carrier gases, pH-controlling agents, organic solvents, hydrophobic agents, enzyme inhibitors, water absorbing polymers, surfactants, absorption promoters and anti-oxidative agents.

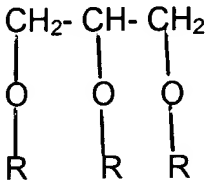
34 (previously amended). The nose-drop package according to claim 29, wherein the monoglyceride preparation is mono-olein and the fatty acid is oleic acid, and the immunizing component is heat-killed *M. tuberculosis* bacteria.

35 (previously presented). The nose-drop package according to claim 29, wherein the composition is formulated into a preparation for mucosal administration.

36 (previously presented). The nose-drop package according to claim 35, wherein the mucosal administration is nasal, pulmonary, oral or vaginal administration.

37 (previously presented). The nose-drop package according to claim 34, wherein the adjuvant further comprises soybean oil.

38 (currently amended). A method of vaccinating a mammal against Tuberculosis (TB) which comprises mucosal administration to the mammal of a protection-inducing amount of a TB vaccine composition comprising ~~as~~ an adjuvant, comprising one or more substances selected from the group consisting of: a) monoglyceride preparations having at least 80% monoglyceride content and having the general formula:



wherein R is H or an acyl group containing from 6 to 24 carbon atoms with the ~~proviso~~ *proviso* that two of the R groups are H; and b) a fatty acid with 6 to 24 carbon atoms; and as immunizing component, inactivated *Mycobacterium tuberculosis* bacteria.

39 (previously amended). The method of vaccinating a mammal against Tuberculosis (TB) according to claim 38, wherein the *M. tuberculosis* bacteria are heat or formalin killed.

40 (previously presented). The method of vaccinating a mammal against Tuberculosis (TB) according to claim 38, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 90% and the acyl chains of the monoglyceride in the monoglyceride preparation contains 8 to 20 carbon atoms.

41 (previously presented). The method of vaccinating a mammal against Tuberculosis (TB) according to claim 38, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 95% and the acyl chains of the monoglyceride in the monoglyceride preparation contains 14 to 20 carbon atoms.

42 (previously presented). The method of vaccinating a mammal against Tuberculosis (TB) according to claim 38, which further comprises pharmaceutical excipients selected from the group consisting of biocompatible oils, physiological saline solutions, preservatives, osmotic pressure pH-controlling agents, carrier gases, PH-controlling agents, organic solvents, hydrophobic agents, enzyme inhibitors, water absorbing polymers, surfactants, absorption promoters and anti-oxidative agents.

43 (previously amended). The method of vaccinating a mammal against Tuberculosis (TB) according to claim 38, wherein the monoglyceride preparation is mono-olein and the fatty acid is oleic acid, and the immunizing component is heat-killed *M. tuberculosis* bacteria.

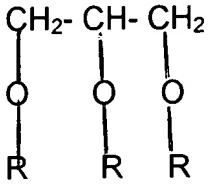
44 (previously presented). The method of vaccinating a mammal against Tuberculosis (TB) according to claim 38, wherein the composition is formulated into a preparation for mucosal administration.

45 (previously presented). The method of vaccinating a mammal against Tuberculosis (TB) according to claim 44, wherein the mucosal administration is nasal, pulmonary, oral or vaginal administration.

46 (previously presented). The method of vaccinating a mammal against Tuberculosis (TB) according to claim 42, wherein the adjuvant further comprises soybean oil.

COPY OF CLEAN CLAIMS

1. A Tuberculosis (TB) vaccine composition comprising an adjuvant comprising one or more substances selected from the group consisting of: a) monoglyceride preparations having at least 80% monoglyceride content and having a formula:



wherein R is H or an acyl group containing from 6 to 24 carbon atoms with the *proviso* that two of the R groups are H and b) a fatty acid with 6 to 24 carbon atoms and as immunizing component, inactivated *Mycobacterium tuberculosis* bacteria.

2. The TB vaccine according to claim 1, wherein the *M. tuberculosis* bacteria are heat or formalin killed.

3. The TB vaccine composition according to claim 1, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 90%, and the acyl chains of the monoglyceride in the monoglyceride preparation contains 8 to 20 carbon atoms.

4. The TB vaccine composition according to claim 1, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 95% and the acyl chains of the monoglyceride in the monoglyceride preparation contains 14 to 20 carbon atoms.

5. The TB vaccine composition according to claim 1, which further comprises pharmaceutical excipients selected from the group consisting of biocompatible oils, physiological saline solutions, preservatives, osmotic pressure controlling agents, carrier gases, pH-controlling agents, organic solvents, hydrophobic agents, enzyme inhibitors, water absorbing polymers, surfactants, absorption promoters and anti-oxidative agents.

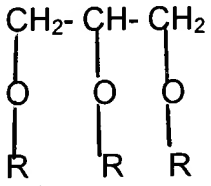
6. The TB vaccine composition according to claim 1, wherein the monoglyceride preparation is mono-olein and the fatty acid is oleic acid, and the immunizing component is heat-killed *M. tuberculosis* bacteria.

7. The TB vaccine composition according to claim 5, wherein the adjuvant further comprises soybean oil.

8. The TB vaccine composition according to claim 1, wherein the composition is formulated into a preparation for mucosal administration.

9. The TB vaccine composition according to claim 8, wherein the mucosal administration is nasal, pulmonary, oral or vaginal administration.

10. An aerosol or spray package comprising a TB vaccine composition comprising an adjuvant comprising one or more substances selected from the group consisting of: a) monoglyceride preparations having at least 80% monoglyceride content and having the formula:



wherein R is H or an acyl group containing from 6 to 24 carbon atoms with the *proviso* that two of the R groups are H, and b) a fatty acid with 6 to 24 carbon atoms, and as immunizing component, inactivated *Mycobacterium tuberculosis* bacteria.

11. An aerosol or spray package according to claim 10, wherein the *M. tuberculosis* bacteria are heat or formalin killed.

12. An aerosol or spray package according to claim 10, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 90%, acyl chains of the monoglyceride in the monoglyceride preparation and contains 8 to 20 carbon atoms.

13. An aerosol or spray package according to claim 10, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 95% and the acyl chains of the monoglyceride preparation contains 14 to 20 carbon atoms.

14. An aerosol or spray package according to claim 10, which further comprises pharmaceutical excipients selected from the group consisting of biocompatible oils, physiological saline solutions, preservatives, osmotic pressure controlling agents, carrier oases, pH-controlling agents, organic solvents, hydrophobic agents, enzyme inhibitors, water absorbing polymers, surfactants, absorption promoters and anti-oxidative agents.

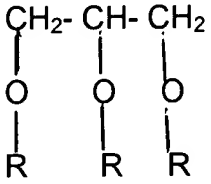
15. An aerosol or spray package according to claim 10, wherein the monoglyceride preparation is mono-olein and the fatty acid is oleic acid, and the immunizing component is heat-killed *M. tuberculosis* bacteria.

16. An aerosol or spray package according to claim 10, wherein the composition is formulated into a preparation for mucosal administration.

17. An aerosol or spray package according to claim 16, wherein the mucosal administration is nasal, pulmonary, oral or vaginal administration.

18. An aerosol or spray package according to claim 15, wherein the adjuvant further comprises soybean oil.

19. A nose-drop package comprising a TB vaccine composition comprising an adjuvant comprising one or more substances selected from the group consisting of: a) monoglyceride preparations having at least 80% monoglyceride content and having the general formula:



wherein R is H or an acyl group containing from 6 to 24 carbon atoms with the *proviso* that two of the R groups are H, and b) a fatty acid with 6 to 24 carbon atoms; and as immunizing component, inactivated *Mycobacterium tuberculosis* bacteria.

20. The nose-drop package, according claims 19, wherein the *M. tuberculosis* bacteria are heat or formalin killed.

21. The nose-drop package according to claim 19, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 90% and the acyl chains of the monoglyceride in the monoglyceride preparation contains 8 to 20 carbon atoms.

22. The nose-drop package according to claim 19, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 95% and the acyl chains of the monoglyceride in the monoglyceride preparation contains 14 to 20 carbon atoms.

23. The nose-drop package according to claim 19, which further comprises pharmaceutical excipients selected from the group consisting of biocompatible oils, physiological saline solutions, preservatives, osmotic pressure controlling agents, carrier gases, pH-controlling agents, organic solvents, hydrophobic agents, enzyme inhibitors, water absorbing polymers, surfactants, absorption promoters and anti-oxidative agents.

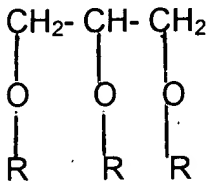
24. The nose-drop package according to claim 19, wherein the monoglyceride preparation is mono-olein and the fatty acid is oleic acid, and the immunizing component is heat-killed *M. tuberculosis* bacteria.

25. The nose-drop package according to claim 19, wherein the composition is formulated into a preparation for mucosal administration.

26. The nose-drop package according to claim 25, wherein the mucosal administration is nasal, pulmonary, oral or vaginal administration.

27. The nose-drop package according to claim 24, wherein the adjuvant further comprises soybean oil.

28. A method of vaccinating a mammal against Tuberculosis (TB) which comprises mucosal administration to the mammal of a protection-inducing amount of a TB vaccine composition comprising an adjuvant comprising one or more substances selected from the group consisting of: a) monoglyceride preparations having at least 80% monoglyceride content and having the general formula:



wherein R is H or an acyl group containing from 6 to 24 carbon atoms with the *proviso* that two of the R groups are H; and b) a fatty acid with 6 to 24 carbon atoms; and as immunizing component, inactivated *Mycobacterium tuberculosis* bacteria.

29. The method of vaccinating a mammal against Tuberculosis (TB) according to claim 28, wherein the *M. tuberculosis* bacteria are heat or formalin killed.

30. The method of vaccinating a mammal against Tuberculosis (TB) according to claim 28, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 90% and the acyl chains of the monoglyceride in the monoglyceride preparation contains 8 to 20 carbon atoms.

31. The method of vaccinating a mammal against Tuberculosis (TB) according to claim 28, wherein the adjuvant has a content of monoglyceride in the monoglyceride preparation of at least 95% and the acyl chains of the monoglyceride in the monoglyceride preparation contains 14 to 20 carbon atoms.

32. The method of vaccinating a mammal against Tuberculosis (TB) according to claim 28, which further comprises pharmaceutical excipients selected from the group consisting of biocompatible oils, physiological saline solutions, preservatives, osmotic pressure pH-controlling agents, carrier gases, pH-controlling agents, organic solvents, hydrophobic agents, enzyme inhibitors, water absorbing polymers, surfactants, absorption promoters and anti-oxidative agents.

33. The method of vaccinating a mammal against Tuberculosis (TB) according to claim 38, wherein the monoglyceride preparation is mono-olein and the fatty acid is oleic acid, and the immunizing component is heat-killed *M. tuberculosis* bacteria.

34. The method of vaccinating a mammal against Tuberculosis (TB) according to claim 28, wherein the composition is formulated into a preparation for mucosal administration.

35. The method of vaccinating a mammal against Tuberculosis (TB) according to claim 34, wherein the mucosal administration is nasal, pulmonary, oral or vaginal administration.

36. The method of vaccinating a mammal against Tuberculosis (TB) according to claim 32, wherein the adjuvant further comprises soybean oil.